

NOT FOR PUBLICATION

FILED UNDER SEAL

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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ALTANA PHARMA AG and WYETH,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.,  
ET AL.,

Defendants.

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CIVIL ACTION NO. 04-2355 (JLL)

**LINARES**, District Judge.

This matter comes before the Court on the renewed motions of Defendant Teva and Defendant Sun ("Defendants") for judgment as a matter of law, that claims 22 and 25 of the '579 patent are invalid for (1) obviousness under 35 U.S.C. § 103 in view of Compound 12 of the '518 patent, (2) double patenting in light of Compound 12 of the '518 patent and (3) double patenting in light of Compound 4 of '230 patent; and in the alternative, for a new trial pursuant to Federal Rule of Civil Procedure 59(a). No oral argument was heard. Fed. R. Civ. P. 78. For the reasons set forth herein, Defendants' motions are denied in their entirety.

**I. BACKGROUND**

A jury trial was conducted from April 5-22, 2010 with respect to Defendant Teva and Defendant Sun ("Defendants"). Simultaneously, a non-jury trial was conducted with respect to Defendant KUDCo. The Court heard testimony from ten witnesses, including seven expert witnesses. Defendants offered testimony from their experts, Dr. David Sherman, Dr. Duan Chen,

Dr. Jeffery Press, and Dr. James Forstner. Defendants also called a named inventor on the '579 patent, Bernard Kohl, as an adverse witness during their case-in-chief. Plaintiffs offered testimony from their experts, Dr. Enar Carlsson, Dr. Richard Killworth, and Dr. Anton Hopfinger. Plaintiffs also offered testimony from a current employee, Geno Germano, and a former employee, George Senn-Bilfinger.

The jury returned a verdict in favor of Plaintiffs as to each issue tried. Subsequently, the Court issued a bench opinion as to Defendant KUDCo ("KUDCo Opinion"). Defendants have renewed their motions for judgment as a matter of law pursuant to Federal Rule of Civil Procedure 50(b) with respect to each of the issues tried to the jury.

## **II. LEGAL STANDARDS**

### **A. Legal Standard: Motion for Judgment as a Matter of Law**

To prevail on a renewed motion for judgment as a matter of law following a jury trial and verdict, the moving party "must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings."<sup>1</sup> Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998) (quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984)). The Federal Circuit defines "substantial evidence" as "such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp., 732 F.2d at 893. The Court

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<sup>1</sup>Despite the Federal Circuit having appellate jurisdiction over this matter, upon a motion for judgment as a matter of law, the Federal Circuit applies the law of the regional circuit. See Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1359 (Fed. Cir. 2006).

should only grant the motion “if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability.” Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153, 1166 (3d Cir. 1993). “In determining whether the evidence is sufficient to sustain liability, the court may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury’s version. Id. (citing Fineman v. Armstrong World Indus., Inc., 980 F.2d 171, 190 (3d Cir. 1992)). Rather, the court must resolve all conflicts of evidence in favor of the non-movant. Williamson v. Consol. Rail Corp., 926 F.2d 1344, 1348 (3d Cir. 1991); Perkin-Elmer Corp., 732 F.2d at 893.

“The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence upon which the jury could properly find a verdict for that party.” Lightning Lube, 4 F.3d at 1166 (quoting Patzig v. O’Neil, 577 F.2d 841, 846 (3d Cir. 1978)). In conducting such an analysis, “the court may not determine the credibility of the witnesses nor ‘substitute its choice for that of the jury between conflicting elements of the evidence.’” Syngenta Seeds, Inc. v. Monsanto Co., 409 F. Supp. 2d 536, 539 (D. Del. 2005) (quoting Perkin-Elmer Corp., 732 F.2d at 893). Generally, the court must determine whether the evidence reasonably supports the jury’s verdict. See Dawn Equip. Co. v. Ky. Farms Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998).

#### **B. Legal Standard Motion for a New Trial**

Federal Rule of Civil Procedure 59(a) provides that:

[t]he court may, on motion, grant a new trial on all or some of the issues – and to any party – as follows: (A) after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court . . .

Fed. R. Civ. P. 59(a). It is within the discretion of the district court whether or not to grant a new trial. Wagner v. Fair Acres Geriatric Ctr., 49 F.3d 1002, 1017 (3d Cir. 1995). Although Rule 59 does not detail the grounds on which a new trial may be granted, the following grounds have been recognized by this Circuit: "the verdict is against the clear weight of the evidence; damages are excessive; the trial was unfair; and that substantial errors were made in the admission or rejection of evidence or the giving or refusal of instructions." Lightning Lube, Inc., 802 F.Supp. 1180, 1186 (D.N.J. 1992), aff'd, 4 F.3d 1153 (3d Cir. 1993).

When reviewing a motion for a new trial, a court must view the evidence in the light most favorable to the party for whom the verdict was returned. Wagner v. Firestone Tire & Rubber Co., 890 F.2d 652, 656 (3d Cir. 1989). Where a motion for a new trial is based primarily on the weight of the evidence, the discretion of the trial court is limited. Klein v. Hollings, 992 F.2d 1285, 1290 (3d Cir. 1993); see also Greenleaf v. Garlock, Inc., 174 F.3d 352, 366 (3d Cir. 1999). Indeed, "new trials because the verdict is against the weight of the evidence are proper only when the record shows that the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be overturned or shocks [the] conscience." Williamson, 926 F.2d at 1353; see also Greenleaf, 174 F.3d at 366. Although a court is permitted to consider the credibility of trial witnesses and to weigh evidence, it must "exercise restraint to avoid usurping the jury's primary function." Hurley v. Atl. City Police Dep't, 933 F. Supp. 396, 403 (D.N.J. 1996), aff'd, 174 F.3d 95 (3d Cir. 1999).

### **III. ANALYSIS**

#### **A. Obviousness Based on Compound 12.**

For the same reasons set forth in the KUDCo Opinion, the Court finds that the jury's

verdict with respect to obviousness based on Compound 12 is both supported by substantial evidence and that the legal conclusions implied by the jury's verdict are supported by those findings. Pannu, 155 F.3d at 1348 (Fed. Cir. 1998). In that opinion, the Court found as follows:<sup>2</sup>

As the parties have stipulated to the scope, content, and level of ordinary skill in the art, Defendant failed to present evidence of a *prima facie* case. First, Defendant failed to produce credible evidence that a person of ordinary skill in the art would have been motivated to select Compound 12 a starting point. More specifically, the Court determined that unlike a person skilled in the art in 1984, Dr. Sherman was afforded the benefit of knowing the desired end result chemical structure prior to choosing Compound 12 as a lead compound and, thus, had the impermissible benefit of hindsight. In contrast, Plaintiff provided ample evidence which indicates that Omeprazole would have been the most logical starting point as of 1984. As of that time it was clear that Omeprazole had been tested in humans. Logically, this fact would make a person skilled in the art look to this drug as a starting point since it had already been deployed for that particular use in humans. As of 1984, Omeprazole was the only PPI that had been tested in humans. (Id. at 8.141:3-7 (Carlsson).) Second, the Court found that the Sachs Article and the Bryson and Perrin references did not, as Defendant contended, provide motivation to modify Compound 12 to obtain Pantoprazole. Finally, the Court found that a person of ordinary skill in the art could not have had a reasonable expectation of success in making that relevant modification because said person would not have been able to reliably predict pKa values.

The above analysis applies with equal force to the instant motions as Defendants (Teva and Sun) rely on the exact same evidence as KUDCo. Therefore, the Court finds that the jury's verdict with respect to obviousness based on Compound 12 is both supported by substantial evidence and that the legal conclusions implied by the jury's verdict are supported by those findings.

Pannu, 155 F.3d at 1348.

Furthermore, because the record evidence supports the conclusion that Defendants failed to establish a *prima facie* case of obviousness, the Plaintiff was not obligated to present evidence of objective indicia of non-obviousness. Thus, to the extent that the jury's findings with regard

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<sup>2</sup> The following is a synopsis of the Court's findings contained in "Section III. A. a. i - iii."

to secondary considerations are inconsistent with this Court's finding in the KUDCo Opinion, such inconsistencies are immaterial.

Defendants' motions with respect to obviousness based on Compound 12 are DENIED as the Court finds that the jury's verdict is both supported by substantial evidence and that the legal conclusions implied by the jury's verdict are supported by those findings. Pannu, 155 F.3d at 1348.

**B. Double Patenting.**

Non-statutory double patenting entails a two-pronged analysis. "First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences." Eli Lilly & Co. V. Barr Labs, 251 F.3d 955, 968 (fed. Cir. 2001) (citing Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1326 (Fed. Cir. 1999)). "Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct." Id. (citing Georgia Pacific, 195 F.3d at 1327). Although the obviousness-type double patenting analysis is analogous to an obviousness analysis under 35 U.S.C. § 103, See Amgen Inc. V. F. Hoffman-LA Roche Ltd., 580 F.3d 1340,1361 (Fed. Cir. 2009), the double patenting analysis does not *require* inquiry into "objective criteria suggesting nonobviousness." Procter & Gamble v. Teva Pharms. USA, Inc., 566 F.3d 989, 999 (Fed. Cir. 2009); see also Geneva Pharms.Inc. v. GlaxoSmithKline PLC, 349 F.3d 1371, 1377 n.1 (Fed. Cir. 2003).

Prior to trial, there was an issue between the parties as to whether or not non-statutory double patenting was a legal question with underlying factual issues to be tried to the Court or to the jury. However, in light of this Court's independent review of the entire record evidence and

subsequent decision as articulated in the KUDCo Opinion, combined with the jury's finding in favor of Plaintiff, it is clear from the record evidence that there is no need to delve into the issue of secondary considerations as Defendants have failed to even demonstrate that (1) Pantoprazole is an obvious modification of Compound 4, (2) there was a reason to modify either Compound 12 or Compound 4, and (3) there was a reasonable expectation of success that by modifying either Compound 12 or Compound 4 one would arrive at Pantoprazole.

**1. Double Patenting Based on Compound 4 of the '230 Patent.**

As stated in the KUDCo Opinion, Defendants failed to produce clear and convincing evidence that (1) Pantoprazole is an obvious modification of Compound 4, (2) that there was a reason to modify Compound 4, and (3) that there was a reasonable expectation of success that by modifying Compound 4 one would arrive at Pantoprazole. More specifically, the Court found as follows:<sup>3</sup>

First, the Court found Defendant's experts (Dr. Chen and Dr. Press) unpersuasive. Dr. Chen's ultimate scientific conclusion that there is a lack of evidence to show that the compounds are different does not prove the opposite conclusion or indicate by clear and convincing evidence that Pantoprazole represents an obvious modification of Compound 4. In addition, Dr. Carlsson credibly challenged Dr. Chen's testing protocol. The Court found Dr. Press's testimony regarding the reason to modify Compound 4 unpersuasive as he presented self-contradictory and inconsistent testimony. Second, the Court found that Defendant failed to prove by clear and convincing evidence that a person of ordinary skill in the art would have reasonably expected success in modifying Compound 4 to arrive at pantoprazole. Here, again, Defendant relied exclusively on the testimony of Dr. Press whose testimony depended on the premise that methyls and hydrogens were functionally equivalent substituents. However, on cross examination, Dr. Press was unable to cite to specific examples supporting his testimony that methyls and hydrogens were functionally equivalent substituents, i.e., that interchanging methyls and hydrogens would have little or no effect on the potency of the compound. (Id. at 6.184:12-17 (Press).) In contrast, Plaintiffs presented credible evidence that interchanging hydrogens or

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<sup>3</sup> The following is a synopsis of the Court's findings contained in "Section III. B. b. i - iii."

methyIs at a particular position to compounds in the prior art produced different, and random, potencies depending on whether the compound included hydrogens or methyIs at a particular position. (Tr. at 9.190:8-201:19; 10.21:11-29:6 (Hopfinger).)

Again, the above analysis equally applies to the instant motion. Thus, Defendants' motions with respect to double patenting based on Compound 4 are DENIED. The Court finds that the jury's verdict with respect to double patenting based on Compound 4 is in this Court's independent review of the entire record of evidence, as articulated in the KUDCo Opinion, supported by substantial evidence and that the legal conclusions implied by the jury's verdict are supported by those findings. Pannu, 155 F.3d at 1348.

Furthermore, because the double patenting analysis does not require inquiry into "objective criteria suggesting nonobviousness," the Court need not address the jury's findings with respect to said criteria. Procter & Gamble, 566 F.3d at 999; see also Geneva Pharms., 349 F.3d at 1377 n.1.

## **2. Double Patenting Based on Compound 12 of the '518 Patent.**

The obviousness-type double patenting analysis and the obviousness analysis under § 103 are parallel. Therefore, the Court finds that the outcome of Defendants' two defenses based on Compound 12 must be the same. As the Court has found that the evidence of record does not support Defendant's § 103 defense based on Compound 12, it likewise does not support a defense of obviousness in light of Compound 12 of the '518 patent. See, e.g., Procter & Gamble, 566 F.3d at 999 ("Having concluded that risedronate was not obvious under 35 U.S.C. § 103, we similarly conclude that the '122 patent is not invalid for obviousness type double patenting."); Sanofi-Synthelabo v. Apotex, Inc., 488 F. Supp. 2d 317, 338 (S.D.N.Y. 2006), aff'd 470 F.3d



1368 (Fed. Cir. 2006) ("If Apotex fails to prove at trial that the '265 patent was obvious in light of the '596 patent as a whole, it has also necessarily failed to prove that the '265 patent was obvious in light of the specific claims of the '596 patent.") This analysis applies to the instant motion. Thus, Defendants' motions with respect to double patenting based on Compound 12 are DENIED. The Court finds that since the jury's verdict with respect the obviousness analysis under § 103 as to Compound 12 is both supported by substantial evidence and that the legal conclusions implied by the jury's verdict are supported by those findings, so too is the jury's finding with respect to Compound 12 of the '518 patent. Pannu, 155 F.3d at 1348.

**C. Motion for a Judgment as a Matter of Law based on Invalidity based on lack of enablement.**

In the alternative, Defendants seek a judgment as a matter of law on the ground that the '579 patent is invalid under 35 U.S.C. § 112 for lack of enablement. In opposition, Plaintiffs argue that such a defense is untimely and not properly preserved as it was not raised prior to trial or contained in the Final Pretrial Order.

Rule 16 dictates that the Final Pretrial Order "controls the course of the action unless the court modifies it" and the Court may make such modification only to "prevent manifest injustice." Fed. R. Civ. P. 16(d), (e). The Court finds that the final pretrial order "controls" the proceedings in that, once entered, it supercedes the pleadings. See Hoagburg v. Harrah's Marina Hotel Casino, 585 F.Supp. 1167, 1175 (D.N.J.1984) (citing Basista v. Weir, 340 F.2d 74, 85 (3d Cir.1965)) (finding that plaintiff had asserted certain claims by including them in the final pretrial order despite the fact that plaintiff had not raised these claims in the complaint).

Here, the Final Pretrial Order does not contain a claim that the claims of 579 patent are

invalid under 35 U.S.C. Section 112 for lack of enablement based on lack of utility. Therefore, Pursuant to Rule 16 this claim is not properly before the Court unless the Court modifies the Final Pretrial Order. The Court finds that such a modification is improper for two reasons. First, Defendants' request is untimely as both the jury and non-jury trials have concluded and the Final Pretrial Order has been discharged. Second, if the Court were to grant the requested relief and rule on the merits of the Defendants' untimely lack of enablement claim, this would result in "manifest injustice" to the Plaintiffs inasmuch as Plaintiffs only received notice of said claim upon the filing of the instant motion and after the close of evidence. Accordingly, Defendants' motion for a judgment as a matter of law based on lack of enablement is DENIED.

#### **D. Motion for a New Trial.**

Defendants move for a new trial based upon the same arguments they presented in favor of their motion for judgment as a matter of law. However, Defendants provide little argument in their submission specific to their "in the alternative" Rule 59(a) motion. Plaintiffs oppose Defendants' motion and argue that the substantial evidence in support of the jury's verdict demonstrates that allowing it to stand would not result in any miscarriage of justice. This Court agrees.

The Court rejects Defendants' contention that the verdict was against the weight of the evidence. Defendants rely upon their arguments for judgment as a matter of law in support of said request. For the same reasons as stated in the previous section of this Opinion, the Court finds that the jury verdict on each of the issues was not "against the weight of the evidence." Based on the evidence presented, the jury acted well within its discretion in finding in favor of Plaintiffs. Defendants have provided no persuasive basis upon which this Court could find that

the verdict amounts to a "miscarriage of justice" or that it "shocks the conscience." Williamson, 926 F.2d at 1353; Greenleaf, 174 F.3d at 366. Accordingly, Defendants' alternate request for a new trial pursuant to Rule 59(a) is DENIED.

### **CONCLUSION**

For the reasons set forth in this Opinion, Defendants' renewed motions for judgment as a matter of law, or in the alternative, for a new trial pursuant to Federal Rule of Civil Procedure 59(a), are denied in their entirety.

An appropriate Order accompanies this Opinion.

DATED: July 15, 2010

/s/ Jose L. Linares  
United States District Judge